

Serial No. 10/555,865

Reply

Attorney Docket No. 105090.61194US

**REMARKS**

Applicants have amended claims 1, 4, 6 and 7.

Claims 1-4, 6 and 7 stand rejected under 35 U.S.C. 112, first paragraph for purportedly being non-enabled.

The Examiner states that the deletion of the words "prevention and/or" from the claims along with deletion of reference to the use of truncated peptides of SEQ ID NO: 2 and 3 would overcome this rejection (Office Action page 5). Although Applicants submit the prior claims are enabled, Applicants have amended the claims to recite a method for the "treatment" of a disease rather than the "prevention and/or treatment" of a disease and have deleted reference to the use of truncated peptides of SEQ ID NO: 2 and 3 from claims 4, 6 and 7.

In view of the foregoing remarks Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 112, first paragraph for lack of enablement.

Claims 1-4, 6 and 7 stand rejected under 35 U.S.C. 102(b) for purportedly being anticipated by WO 00/72880A2 ("Schenk") for the reasons of record. Claims 1-4, 6 and 7 also stand rejected under 35 U.S. C. 102(e) for purportedly being anticipated by US 2006/0188512A1 ("Yednock") also for the reasons of record. Applicants disagree and in view of the following remarks and amendments to the claims request that the Examiner reconsider and withdraw the rejection.

Both Schenk and Yednock fail to disclose each and every element of the invention as claimed.

Anticipation under 35 U.S.C. §102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention.

*Electro Med. Sys. S.A. v. Cooper Life Sciences*,  
32 USPQ2d 1017, 1019 (Fed. Cir. 1994).

Page 8 of 12

DCACTIVE-14250096.1

Serial No. 10/555,865

Reply

Attorney Docket No. 105090.61194US

Applicants submit that a method using SEQ ID 2 or 3 as immunogens to treat amyloid disease is neither taught nor suggested by Schenk or Yednock.

Claims 1-4, 6 and 7 stand rejected under 35 U.S.C. 102(b) for purportedly being anticipated by WO 00/72880A2 ("Schenk") for the reasons of record. In particular, the Examiner states that Schenk discloses that the immunogenic fragments of A $\beta$  have a sequence of no more than 10, 9, 8, 7 or 5 contiguous residues in length and can include such A $\beta$  peptide fragments as A $\beta$  35-40, A $\beta$  35-42 and A $\beta$  33-42 (Office Action of 09/28/2009 page 13). However, Applicant direct the Examiner's attention to Schenk's Table 5, which teaches that peptide A $\beta$ 33-42 (SEQ ID No. 3 in the present application) is not capable of stimulating an immune response (see page 19, which is reproduced below):

conjugate, A $\beta$ 13-28 conjugate and A $\beta$ 25-35 proliferated in response to A $\beta$ 1-40. The remaining groups receiving A $\beta$ 1-5 conjugate, A $\beta$ 33-42 conjugate pBx6 or PBS had no animals with an A $\beta$ -stimulated response. These results are summarized in Table 5 below.

Table 5			
Immunogen	Conjugate	A $\beta$ Amino Acids	Responders
A $\beta$ 1-5	Yes	5-mer	0/7
A $\beta$ 1-12	Yes	12-mer	1/8
A $\beta$ 13-28	Yes	16-mer	1/9
A $\beta$ 25-35		11-mer	1/9
A $\beta$ 33-42	Yes	10-mer	0/10
A $\beta$ 1-40		40-mer	5/8
A $\beta$ 1-42		42-mer	9/9
r A $\beta$ 1-42		42-mer	8/8
pBx6			0/8
PBS		0-mer	0/8

As such, the activity of SEQ ID 3 (A $\beta$  33-42) as an immunogen is not taught by Schenk because Schenk demonstrates that this peptide was unable to trigger an immune response in animals. There is no teaching that a peptide of SEQ ID NO:2 would serve as an immunogen. Therefore Schenk fails to teach

Serial No. 10/555,865

Reply

Attorney Docket No. 105090.61194US

this element of the claims and fails to anticipate the invention as claimed in claims 4, 6 and 7.

In view of the foregoing remarks, Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 102(b) in view of Schenk.

Claims 1-4, 6 and 7 stand rejected under 35 U.S. C. 102(e) for purportedly being anticipated by US 2006/0188512A1 ("Yednock") also for the reasons of record. In particular, the Examiner states that Yednock teaches that C-terminal fragments of A $\beta$  42 of 5-10 or preferably 7-10 contiguous amino acids are considered for peptide immunogens and that Yednock discloses administering an effective regimen of a fragment of A $\beta$  such as A $\beta$  33-42 or A $\beta$  35-40 for induction of an immune response for therapy citing to Yednock's claim 48 at p. 25.

However, Yednock merely mentions the use of fragments from central or C-terminal regions of A $\beta$  but does not teach a method of treatment of amyloid diseases by using, in particular, SEQ ID 2 and 3. See e.g. page 2, paragraph [0009] which is reproduced below:

#### I. General

[0009] The invention provides methods of preventing, effecting prophylaxis of, or treating a disease associated with amyloid deposits using fragments from a central or C-terminal regions of A $\beta$ . Such fragments can induce a polyclonal mixture of antibodies that specifically bind to soluble A $\beta$  without binding to plaques. The antibodies can inhibit formation of amyloid deposits of A $\beta$  in the brain of a patient from soluble A $\beta$ , thus preventing or treating the disease. Fragment A $\beta$  15-24 and subfragments of 5-10 contiguous amino acids thereof are preferred immunogens due to their capacity to generate a high titer of antibodies.

In addition, Yednock's Claim 48 expressly excludes a peptide that would induce antibodies that would specifically bind to an A $\beta$  33-42 or A $\beta$  35-40. Claim 48 teaches a method of treating a disease comprises administering a fragment of

Page 10 of 12

DCACTIVE-14250096.1

Serial No. 10/555,865

Reply

Attorney Docket No. 105090.61194US

A $\beta$  wherein the fragment induces antibodies that specifically bind to A $\beta$  at one or more epitopes between residues 12 and 43 without inducing antibodies that specifically bind to one or more epitopes between residues 1-11 and the fragment 33-42 A $\beta$  18-28, 17-28, 25-35, 35-40 or 35-42.

Furthermore, fragments A $\beta$  33-42 and 35-40 are also explicitly excluded from the A $\beta$  fragments recited in Yednock's Claim 1 to treat an amyloid disease:

1. A method of prophylaxis of a disease associated with amyloid deposits of A $\beta$  in the brain of a patient, comprising administering an effective regime of a fragment of A $\beta$ , wherein the fragment induces antibodies that specifically bind to A $\beta$  at one or more epitopes between residues 12 and 43 without inducing antibodies that specifically bind to one or more epitopes between residues 1-11, and the fragment is not A $\beta$  18-28, 17-28, 25-35, 35-40, 33-42 or 35-42, whereby the induced antibodies specifically bind to soluble A $\beta$  in the patient thereby inhibiting formation of amyloid deposits of A $\beta$  in the brain from the soluble A $\beta$ , and thereby effecting prophylaxis of the disease.

Thus Yednock does not teach a method for treating a disease with peptides of SEQ ID NO: 2 or 3.

Because Yednock fails to each and every limitation of the invention as claimed, Yednock therefore fails to anticipate the claimed invention and Applicants request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 102(e) in view of Yednock.

Serial No. 10/555,865

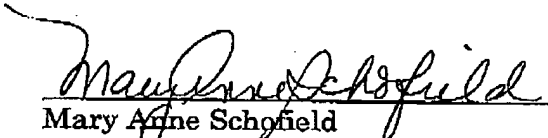
Reply

Attorney Docket No. 105090.61194US

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323, Docket No. 105090.61194US.

Respectfully submitted,

January 7, 2011

  
Mary Anne Schofield  
Registration No. 36,669

CROWELL & MORING LLP  
Intellectual Property Group  
P.O. Box 14300  
Washington, DC 20044-4300  
Telephone No.: (202) 624-2500  
Facsimile No.: (202) 628-8844